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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/915,178 | 07/24/2001 | D. Wade Walke | LEX-0205-USA | 5253 |

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| EXAMINER | |
|---|---|
| PROUTY, REBECCA E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | 6 |

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/915,178 | Applicant(s) Walke et al. |
|---|---|---|
| | Examiner Rebecca Prouty | Art Unit 1652 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above, claim(s) 4 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to nucleic acids and vectors encoding a human β-thymosin peptide, classified in class 435, subclass 320.1.

II. Claim 4, drawn to a human β-thymosin peptide, classified in class 530, subclass 324.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I and the proteins of Group II are patentably distinct compounds because they are chemically different, the DNA has other utility besides encoding the proteins such as a hybridization probe and the proteins can be made by another method such as isolation from natural sources or chemical synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Peter Seferian on 6/4/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this

election must be made by applicant in replying to this Office action. Claim 4 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "first disclosed in the NHP sequence described in SEQ ID NO:1 and expressing the amino acid sequence shown in SEQ ID NO:2" as one can not determine the scope of fragments being claimed. Is this claim limited to only nucleic acids containing particular fragments of SEQ ID NO:1 or does it include nucleic acids comprising an fragment of SEQ ID NO:1 of at least 24 bases? Must the claimed nucleic acid encode SEQ ID NO:2 or is the recitation "expressing

the amino acid sequence shown in SEQ ID NO:2" descriptive of SEQ ID NO:1 only? For examination purposes this claim in presumed to cover any cDNA molecule comprising 24 contiguous bases of SEQ ID NO:1. Further, the use of abbreviations within the claims, without first identifying what the abbreviation stands for is unclear.

Claim 2 is indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While page 3 of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene of SEQ ID NO:1, a sequence must be to be included within the scope of these claims.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This claim is directed to a genus of DNA molecules comprising at least 24 contiguous bases of SEQ ID NO:1.

The specification does not contain any disclosure of the function of all DNA sequences that comprise at least 24 contiguous bases of SEQ ID NO:1. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:2, does not reasonably provide enablement for

any nucleic acid comprising 24 contiguous bases of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass any cDNA comprising at lest 24 contiguous nucleotides of SEQ ID NO:1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of cDNAs broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a particular nucleic acid determines its structural and functional properties, predictability of which changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence of SEQ ID NO:1 and the protein it encodes, i.e., SEQ ID NO:2.

While recombinant and mutagenesis techniques are known, it is <u>not</u> routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and

the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any cDNA comprising at least 24 contiguous residues of SEQ ID NO:1 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting β-thymosin activity; (B) the general tolerance of β-thymosin genes to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any β-thymosin residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the

scope of the claims broadly including any cDNA comprising at least 24 bases of SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Spytek et al. (WO 01/90155).

Spytek et al. teach a nucleic acid (SEQ ID NO:3) and its encoded protein (SEQ ID NO:4) which comprises sequences 100%

identical to SEQ ID NO:1 and SEQ ID NO:2 of the instant application and vectors encoding this nucleic acid. SEQ ID NOS:3 and 4 of Spytek et al. were first disclosed in US provisional application 60/206,688. As such the effective filing date of Spytek et al. for the subject matter of SEQ ID NOS:3 and 4 is 5/24/00 and Spytek et al. anticipate the current claims.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession No. AW620090.

GenBank Accession No. AW620090 teach a sequence comprising 25 consecutive nucleotides of SEQ ID NO:1. Nucleotides 98-122 of GenBank Accession No. AW620090 are identical to nucleotides 33-57 of SEQ ID NO:1.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hannappel et al. and Zetter et al. disclose a variety of β-thymosin peptides and teach that this class of peptides all bind to and sequester actin and thus inhibit actin polymerization. Safer et al. teach that the polymerization/depolymerization of actin plays a fundamental role in cell locomotion and the assembly and remodeling of the cytoskeleton during growth processes. As such an ordinary skilled artisan would find such peptides useful as research tools for the study of processes involving actin polymerization.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652